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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
DEVI,S	
ART UNIT	**PAPER NUMBER**
1645	13

DATE MAILED: 12/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/077,574	Panaccio et al.
Examiner	**Group Art Unit**
S. Devi, Ph.D.	1645

☒ Responsive to communication(s) filed on *10/17/00.*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-62, 77, and 91-93* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-62, 77 and 91-93* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____.

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Lack of Unity of Invention

1) Claims 63-76 and 78-90 have been canceled via the amendment filed 06/01/98.

Claims 1-15, 32, 37 and 40 were amended via the amendment filed 06/01/98.

New claim 91 was added via the amendment filed 06/01/98.

Claims 2-31, 33-62, 77 and 91 have been amended via the amendment filed 08/03/00 (paper no. 9).

New claims 92 and 93 have been added via the amendment filed 08/03/00 (paper no. 9).

It is unclear what the differences are between claims 51 and 62 with regard to SEQ ID NO: 25.

Claims 1-62, 77 and 91-93 are under prosecution.

2) **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3) Lack of unity / restriction to one of the following inventions is required under PCT Rule 13.1 and 13.2:

1. Claims 2-5 and 33-36, drawn to a vaccine comprising a non-pathogenic form of *Lawsonia intracellularis* or related microorganism and a method of vaccinating an animal by administering the same, classified in class 424, subclass 93.4.
2. Claims 10, 12, 41 and 43, drawn to a vaccine composition comprising the polypeptide GroEL having an amino acid sequence of SEQ ID NO: 2 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.
3. Claims 11, 13, 42 and 44, drawn to a vaccine composition comprising the

polypeptide GroES having an amino acid sequence of SEQ ID NO: 4 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

4. Claims 14 and 45, drawn to a vaccine composition comprising a polypeptide encoded by a polynucleotide comprising SEQ ID NO: 5 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

5. Claims 15 and 46, drawn to a vaccine composition comprising a polypeptide encoded by a polynucleotide comprising SEQ ID NO: 6 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

6. Claims 16 and 47, drawn to a vaccine composition comprising a polypeptide encoded by a polynucleotide comprising SEQ ID NO: 9 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

7. Claims 17 and 48, drawn to a vaccine composition comprising a polypeptide encoded by a polynucleotide comprising SEQ ID NO: 12 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

8. Claims 18 and 49, drawn to a vaccine composition comprising a polypeptide encoded by a polynucleotide comprising SEQ ID NO: 15 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

9. Claims 19 and 50, drawn to a vaccine composition comprising a polypeptide encoded by a polynucleotide comprising SEQ ID NO: 21 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

10. Claim 20, drawn to a vaccine composition comprising a polypeptide encoded by a polynucleotide comprising SEQ ID NO: 28, classified in class 530, subclass 350.

11. Claims 21 and 52, drawn to a vaccine composition comprising a polypeptide encoded by a polynucleotide comprising SEQ ID NO: 29 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

12. Claims 22 and 53, drawn to a vaccine composition comprising a polypeptide encoded by a polynucleotide comprising SEQ ID NO: 30 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

13. Claims 23 and 54, drawn to a vaccine composition comprising a polypeptide encoded by a polynucleotide comprising SEQ ID NO: 31 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

14. Claims 24 and 55, drawn to a vaccine composition comprising a polypeptide encoded by a polynucleotide comprising SEQ ID NO: 32 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

15. Claims 25 and 56, drawn to a vaccine composition comprising a polypeptide encoded by a polynucleotide comprising SEQ ID NO: 33 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

16. Claims 26 and 57, drawn to a vaccine composition comprising a polypeptide comprising SEQ ID NO: 7 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

17. Claims 26 and 57, drawn to a vaccine composition comprising a polypeptide comprising SEQ ID NO: 8 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

18. Claims 27 and 58, drawn to a vaccine composition comprising a polypeptide comprising SEQ ID NO: 10 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

19. Claims 28 and 59, drawn to a vaccine composition comprising a polypeptide comprising SEQ ID NO: 11 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.
20. Claims 29 and 60, drawn to a vaccine composition comprising a polypeptide comprising SEQ ID NO: 13 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.
21. Claims 29 and 60, drawn to a vaccine composition comprising a polypeptide comprising SEQ ID NO: 14 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.
22. Claims 30 and 61, drawn to a vaccine composition comprising a polypeptide comprising SEQ ID NO: 17 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.
23. Claims 30 and 61, drawn to a vaccine composition comprising a polypeptide comprising SEQ ID NO: 18 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.
24. Claims 30 and 61, drawn to a vaccine composition comprising a polypeptide comprising SEQ ID NO: 19 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.
25. Claims 30 and 61, drawn to a vaccine composition comprising a polypeptide comprising SEQ ID NO: 20 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.
26. Claims 31 and 62, drawn to a vaccine composition comprising a polypeptide comprising SEQ ID NO: 22 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.
27. Claims 31 and 62, drawn to a vaccine composition comprising a polypeptide comprising SEQ ID NO: 24 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.
28. Claims 31, 51 and 62, drawn to a vaccine composition comprising a polypeptide comprising SEQ ID NO: 25 and a method of vaccinating an animal by

administering the same, classified in class 530, subclass 350.

29. Claims 31 and 62, drawn to a vaccine composition comprising a polypeptide comprising SEQ ID NO: 26 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

30. Claims 31 and 62, drawn to a vaccine composition comprising a polypeptide comprising SEQ ID NO: 27 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

31. Claims 92 and 93, drawn to a vaccine composition comprising a polypeptide encoded by a nucleotide sequence comprising SEQ ID NO: 34 and a method of vaccinating an animal by administering the same, classified in class 530, subclass 350.

32. Claims 77 and 91, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 1, classified in class 536, subclass 23.7.

33. Claims 77 and 91, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 3, classified in class 536, subclass 23.7.

34. Claims 77 and 91, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 5, classified in class 536, subclass 23.7.

35. Claims 77 and 91, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 6, classified in class 536, subclass 23.7.

36. Claims 77 and 91, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 9, classified in class 536, subclass 23.7.

37. Claims 77 and 91, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 12, classified in class 536, subclass 23.7.

38. Claims 77 and 91, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 15, classified in class 536, subclass 23.7.

39. Claims 77 and 91, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 17, classified in class 536, subclass 23.7.

40. Claims 77 and 91, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 18, classified in class 536, subclass 23.7.

41. Claims 77 and 91, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 19, classified in class 536, subclass 23.7.

42. Claims 77 and 91, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 20, classified in class 536, subclass 23.7.

43. Claims 77 and 91, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 28, classified in class 536, subclass 23.7.

44. Claims 77 and 91, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 29, classified in class 536, subclass 23.7.

45. Claims 77 and 91, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 30, classified in class 536, subclass 23.7.

46. Claims 77 and 91, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 31, classified in class 536, subclass 23.7.

47. Claim 77, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 32, classified in class 536, subclass 23.7.

48. Claims 77 and 91, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 33, classified in class 536, subclass 23.7

49. Claims 77 and 91, drawn to a genetic vaccine comprising a polynucleotide comprising SEQ ID NO: 34, classified in class 536, subclass 23.7

Claims 1 and 32 are considered linking claim and would be joined with one of inventions 1 through 31, if elected.

Claims 6-9 and 37 are considered linking claims and would be joined with one of inventions 2 through 31, if elected and if polypeptide species in claims 6 and 37 is elected.

Claim 40 is considered a linking claim and would be joined with one of inventions 2 and 3, if elected.

Claims 38 and 39 are considered linking claims and would be joined with one of inventions 2 through 31, if elected.

4) Inventions 1 through 49 lack unity of invention due to the absence of a special technical feature unifying the inventions. Invention 1 is drawn to the first product and a method of using the product, which is a permitted combination under PCT Rule 13.2. However, inventions 2

through 31 are drawn to vaccines comprising various polypeptides having structurally, biologically and immunogenically distinct amino acid sequences and a method of using the same. Inventions 32 through 49 are drawn to vaccines comprising various polynucleotides having structurally, biologically and immunogenically distinct nucleotide sequences. The various polypeptides or amino acid sequences of inventions 2 through 31 are distinct from one another in their content of amino acid residues and immunogenic and/or biologic effects, each having its own utility. Similarly, the various DNA sequences of inventions 32 through 49 are distinct each from the other in their content of nucleic acid residues and immunogenic and/or biologic effects, each having its own utility. Clearly, the special technical feature of inventions 1 through 49 is not a unifying feature.

Although polypeptides of inventions 2 through 31 belong to the same class/subclass, these polypeptides comprise sequences that are structurally or chemically distinct from one another, thus requiring non-coextensive searches. Similarly, although polynucleotides of inventions 32 through 49 belong to the same class/subclass, these polynucleotides comprise sequences that are structurally or chemically distinct from one another, thus requiring non-coextensive searches.

Because these inventions are distinct for the reasons given and have acquired a separate status in the art as shown by their different classification/subclassification and divergent subject matter, restriction for examination purposes as indicated is proper.

5) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

6) This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claim 6 is generic to a plurality of disclosed patentably distinct species comprising macromolecules:

A. Polypeptide (class 530, subclass 350);

B. Carbohydrate (class 514, subclass 23);

C. Lipid (class 424, subclass 283.1) and

D. Nucleic acid (class 536, subclass 23.7).

Claim 37 is generic to a plurality of disclosed patentably distinct species comprising immunogenic components:

A. Peptide, protein or polypeptide (class 530, subclasses 350 and 300)

B. Carbohydrate (class 514, subclass 23);

C. Lipid (class 424, subclass 283.1) and

D. Nucleic acid (class 536, subclass 23.7).

Claims 9 and 40 are generic to a plurality of disclosed patentably distinct species comprising compounds or immunogenic components:

A. S-adenosylmethionine (class 436, subclass 86)

B. Heatshock protein and flagellar basal body rod protein (class 530, subclass 825)

C. Enoyl-(acyl-carrier-protein) reductase (class 424, subclass 94.4)

D. tRNA ribosyltransferase-isomerase (class 424, subclass 94.5)

E. Autolysin (class 424, subclass 234.1)

F. Glucarate transporter (class 424, subclass 234.1)

Applicants are required, in reply to this action, to elect a single disclosed species even though this requirement is traversed.

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record, showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C 103(a) of the other invention.

7) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R 1.48(b) and by the fee required under 37 C.F.R 1.17(h).

8) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. The Examiner

can normally be reached on Monday to Friday from 7.30 a.m. to 4.30 p.m. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 309-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SD
S. Devi, Ph.D.
Patent Examiner
December, 2000

RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

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PAGES, INCLUDING COVERSHEET:

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TO EXAMINER: S. DEVI, Ph.D.

ART UNIT: 1645

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